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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,049	10/02/2001	Chih-Ming Chen	300.1033US	8670

23280 7590 04/08/2003

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,049

Applicant(s)

CHEN, CHIH-MING

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Assargren *et al.*

(WIPO Publication No. 98/00351)

Assargren *et al.* disclose blister packs that may be used to two drugs, such as a proton pump inhibitor and at least one antibiotic. Omeprazole is listed as an example of a proton pump inhibitor (See Abstract; and Page 8, Lines 16-23). Various antibiotics are listed, including bismuth subsalicylate and colloidal bismuth subcitrate. Combinations of the listed antibiotics may also be used (See Page 8, Line 25 to Page 9, Line 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eek (WIPO Publication No. WO 88/02342) in view of Depui *et al.* (U.S. Patent No. 6,365,184 B1)

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The Eek document discloses drug packaging consisting of blister pack cards that may be assembled to form a combination pack of dosage forms, such as tablets (See Abstract; Page 1, Lines 5-12; and Figures). The scope of the disclosed invention encompasses dosage units of different drugs or different amounts of drugs within a single blister pack (See Page 5, Lines 8-14). Digital notation may be printed on the pack for the benefit of the patient. Alternatively, other notation may be printed, such as the time of day or the day of the week for the dose to be taken (See Page 7, Lines 7-11). Methods of treating disease using a combination blister pack are also disclosed (See Page 5, Lines 1-6).

The Eek document does not explicitly disclose the use of the disclosed pack with a combination of a proton pump inhibitor and a non-steroidal anti-inflammatory drug.

The Depui *et al.* patent teaches a drug combination comprising a proton pump inhibitor and a non-steroidal anti-inflammatory drug (See Abstract). Omeprazole and diclofenac are given as suitable drugs for use in this combination (See Column 6, first structure; Column 8, Lines 9-13; and Example 6). The use of these drugs in separate dosage forms in a combination therapy in the prior art is acknowledged in the disclosure (See Column 2, Lines 32-40).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of Eek and Depui *et al.* into the objects of the instantly claimed invention. It is the position of the examiner that one of ordinary skill would be motivated to combine the disclosures of Eek and Depui *et al.* in order to create a packaging system that will increase the likelihood of patient compliance. As stated in Depui *et al.*, the motivation to create the disclosed combination dosage form originates from a desire to give a patient a composition that is convenient to take, leading to greater compliance. It is the position

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of the examiner that similarly, a combination dosage regimen given in one package will also lead to greater patient compliance. As the disclosed invention of Eek is not limited to any particular types of drugs to be packaged, one of ordinary skill can expect to create a drug pack comprising dosages of omeprazole and diclofenac in accordance with a combination dosage regimen with a reasonable expectation of success. Claim limitations in Claims 1-3 and 19 drawn to the types of dosage forms to be packaged therein essentially amount, in the view of the examiner, to a recitation of the future intended use of the claimed invention. Such a recitation must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claim 10, drawn to a packaging system containing dosages for human patients, also contain a recitation of future intended use of the instantly claimed invention. Claims 16, 17, and 20, drawn to limitations of the amount of doses defined in a number of days' supplies, are not found to be patentable in view of the prior art, as Eek teaches how the disclosed packaging system can be designed to carry more than one day's worth of doses for a combination treatment (See Page 7, Lines 7-11). The examiner considers it to be easily within the purview of one of ordinary skill in the art to design a packaging system in accordance to what is disclosed by the prior art to contain doses lasting anywhere up to 28 days, or between 7 to 14 days, as claimed in the instant application. Similarly, it is the position of the examiner that one of ordinary skill in the art would find Claim 18, which provides for at least one dose of a third drug, obvious in view of the prior art, as different drugs may be provided in the packaging system of Eek within a single blister pack,

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presumably before it is assembled in combination with another blister pack containing a third drug. Thus, the instantly claimed invention is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjoh
April 1, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600